

House Bill 2754

Sponsored by Representatives SALINAS, NOSSE

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**.

Requires pharmacy or pharmacist to substitute prescribed biological product with interchangeable biological product.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to pharmaceutical substitutions; creating new provisions; amending ORS 689.522; and de-
3 claring an emergency.

4 **Be It Enacted by the People of the State of Oregon:**

5 **SECTION 1.** ORS 689.522 is amended to read:

6 689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product [*may*
7 *not*] **shall** substitute a biological product for the prescribed biological product [*unless*] **if**:

8 (a) The substitute biological product has been determined by the United States Food and Drug
9 Administration to be interchangeable with the prescribed biological product;

10 (b) The prescribing practitioner has not designated on the prescription that substitution is pro-
11 hibited;

12 (c) The patient for whom the biological product is prescribed is informed of the substitution in
13 a manner reasonable under the circumstances; and

14 (d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than
15 three years.

16 (2) Not later than five business days after the dispensing of a biological product, the pharmacy
17 or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dis-
18 pensed to the patient, including the name and manufacturer of the biological product, by making an
19 entry into an electronic system that the prescribing practitioner can access electronically and that
20 is:

21 (a) An interoperable electronic medical records system;

22 (b) An electronic prescribing technology;

23 (c) A pharmacy benefit management system; or

24 (d) A pharmacy record.

25 (3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an
26 electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the
27 pharmacist's designee, shall communicate not later than five business days to the prescribing prac-
28 titioner the specific biological product dispensed to the patient, including the name and manufac-
29 turer of the biological product. The communication may be by facsimile, electronic mail, telephone
30 or another method.

31 (4) If the biological product is dispensed to a patient in a clinic, community-based care facility,

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

1 hospital or long term care facility, an entry made to the patient’s medical record of the specific bi-
 2 ological product dispensed to the patient, including the name and manufacturer of the biological
 3 product, satisfies the communication requirements of subsections (2) and (3) of this section.

4 (5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the
 5 pharmacist’s designee, is not required to communicate to the prescribing practitioner the specific
 6 biological product dispensed to the patient if:

7 (a) The United States Food and Drug Administration has not approved an interchangeable bi-
 8 ological product for the prescribed biological product;

9 (b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is
 10 dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist
 11 filled or refilled the patient’s prescription; or

12 (c) The pharmacy or pharmacist is filling a prescription for a vaccine.

13 (6) The entries described in subsections (2) and (4) of this section or the communication de-
 14 scribed in subsection (3) of this section provides notice to the prescribing provider of the dispensa-
 15 tion of a biological product to a patient.

16 (7) The State Board of Pharmacy shall, on a website maintained by the board, maintain a link
 17 to the current list, if available, of biological products determined by the United States Food and
 18 Drug Administration to be interchangeable.

19 (8)(a) For purposes of this section, the board shall adopt by rule definitions for the terms “bi-
 20 ological product” and “interchangeable.”

21 (b) The rule defining the term “biological product” must be consistent with 42 U.S.C. 262(i)(1).

22 (c) The rule defining the term “interchangeable” must:

23 (A) For biological products licensed under the Public Health Service Act, define the biological
 24 products that may be substituted for other biological products as having been determined by the
 25 United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

26 (B) For biological products approved by the United States Food and Drug Administration under
 27 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that
 28 may be substituted for other biological products as having been determined by the United States
 29 Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or
 30 supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

31 **SECTION 2.** ORS 689.522, as amended by section 2, chapter 43, Oregon Laws 2016, is amended
 32 to read:

33 689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product [*may*
 34 *not*] **shall** substitute a biological product for the prescribed biological product [*unless*] **if**:

35 (a) The substitute biological product has been determined by the United States Food and Drug
 36 Administration to be interchangeable with the prescribed biological product;

37 (b) The prescribing practitioner has not designated on the prescription that substitution is pro-
 38 hibited;

39 (c) The patient for whom the biological product is prescribed is informed of the substitution in
 40 a manner reasonable under the circumstances; and

41 (d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than
 42 three years.

43 (2) The State Board of Pharmacy shall, on a website maintained by the board, maintain a link
 44 to the current list, if available, of biological products determined by the United States Food and
 45 Drug Administration to be interchangeable.

1 (3)(a) For purposes of this section, the board shall adopt by rule definitions for the terms “bi-
2 ological product” and “interchangeable.”

3 (b) The rule defining the term “biological product” must be consistent with 42 U.S.C. 262(i)(1).

4 (c) The rule defining the term “interchangeable” must:

5 (A) For biological products licensed under the Public Health Service Act, define the biological
6 products that may be substituted for other biological products as having been determined by the
7 United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

8 (B) For biological products approved by the United States Food and Drug Administration under
9 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that
10 may be substituted for other biological products as having been determined by the United States
11 Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or
12 supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

13 **SECTION 3. The amendments to ORS 689.522 by sections 1 and 2 of this 2019 Act apply
14 to biological products prescribed on and after the operative date of this 2019 Act.**

15 **SECTION 4. (1) The amendments to ORS 689.522 by sections 1 and 2 of this 2019 Act be-
16 come operative on January 1, 2020.**

17 **(2) The State Board of Pharmacy may take any action before the operative date specified
18 in subsection (1) of this section that is necessary to enable the board to exercise, on and
19 after the operative date specified in subsection (1) of this section, all of the duties, functions
20 and powers conferred on the board by the amendments to ORS 689.522 by sections 1 and 2
21 of this 2019 Act.**

22 **SECTION 5. This 2019 Act being necessary for the immediate preservation of the public
23 peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect
24 on its passage.**